



# **Candidate Vaccine Strains and Potency Reagents for 2017-18 Influenza Season**

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## Topics to Be Covered

- **Currently used vaccine strains and WHO recommendation for 2017 – 18 Seasonal Vaccines (Trivalent and Quadrivalent)**
- **Available Reagents for each of the strains**
- **General Comments**

# Influenza A (H1N1)

- **Current Vaccine Strain (2016-17 Season) : A/California/7/2009 (H1N1)pdm09-like virus**
  - A/California/7/2009(H1N1): reassortants X-179A, X-181
  - A/Christ Church/16/2010 (H1N1): reassortants NIB-74 & NIB-74xp
  - A/Brisbane/10/2010 (H1N1): Wild type (Wt.)
  - **Reagents made available: X-179A & X-181(egg): CBER,**  
NIB-74 (egg): *NIBSC*  
A/Brisbane/10/2010 Wt.(Cell): *NIBSC*
  
- **WHO Recommended Strain for 2017-18: A/Michigan/45/2015 (H1N1)pdm09-like virus**
  - **Candidate Vaccine Viruses:** A/Singapore/GP1908/2015 (Wt., IVR-180 & IVR-180A); A/Slovenia/2903/2015 (NIB-96); A/Scotland/P2/2015 (Wt. & NIB-97); A/Lisboa/32/2015 (Wt. & NIB-98); A/Michigan/45/2015 (Wt., NYMCX-275 & NYMCX-275A)
  - Recommended for 2017 southern hemisphere (SH) season

# Available Reagents for H1N1

- **Reference Antigen**
  - **For Egg Derived**
    - **A/Michigan/45/2015 X-275 CBER Reference Antigen (Lot 85).....calibration planned**
    - *A/Michigan/45/2015 X-275: NIBSC\**
    - *A/Singapore/GP1908/2015 IVR-180: TGA\* & NIBSC\**
  - **For Cell Derived**
    - *A/Singapore/GP1908/2015 Wt. (Cell Derived): TGA\**
- **CBER Antiserum**
  - **H1-Ab-17XX (antiserum preparation in progress)**

*\*(CBER approval of these reagents: case by case basis)*

# Influenza A (H3N2)

- **Current Vaccine Strain (2016–17 Season) : A/Hong Kong/4801/2014 (H3N2)-like virus**
  - A/Hong Kong/4801/2014: (X-263B)
  - A/Hong Kong/4801/2014
  - **Reagents made available: X-263B (egg): CBER & NIBSC**  
**A/Hong Kong/4801/2014 (cell): CBER**
  
- **WHO Recommended Strain for 2017–18: A/Hong Kong/4801/2014 (H3N2)-like virus**
  - **Candidate Vaccine Viruses (egg derived):** A/Victoria/673/2014 (Wt. & NIB-92); A/New Caledonia/71/2014 (Wt., NIB-91, IVR-178 & X-257A); A/Hong Kong/7127/2014 (Wt., NIB-93, NIB-94 & X-261); A/Hong Kong/4801/2014 (Wt., X-263, X-263A & X-263B) and A/Norway/2178/2014 (NYMC X-273); A/Saitama/103/2014 (Wt.)
  - **Candidate Vaccine Viruses (cell culture-derived):** A/Singapore/GP2050/2015; A/Hawaii/47/2014
  - Has been recommended for 2017 southern hemisphere (SH) season

# Available Reagents for H3N2

- **Reference Antigen**
  - **For Egg Derived**
    - **A/Hong Kong/4801/2014 (X-263B): CBER Lot 84....is available**
    - *A/Hong Kong/4801/2014 (X-263B): NIBSC\* & TGA\**
    - *A/Hong Kong/4801/2014 (X-263): NIID\**
    - *A/New Caledonia/71/2014 (X-257A): TGA\**
  - **For Cell Derived**
    - **A/Hong Kong/4801/2014: CBER Lot H3-Ag-1603....is available**
- **CBER Antiserum**
  - **H3-Ab-1611**
  - **H3-Ab-1612**

*\*(CBER approval of these reagents: case by case basis)*

# Influenza B (Victoria Lineage)

- **Current Vaccine Strain (2016–17 Season): Victoria lineage-B/Brisbane/60/2008-like virus**
  - B/Brisbane/60/2008: Wt.
  - B/Hong Kong/259/2010
  - **Reagents made available: B/Brisbane/60 Wt. (egg): CBER, NIBSC\* & TGA\***
    - B/Hong Kong/259/2010 (cell): CBER**
    - B/Brisbane/60 (cell): CBER**
    - B/Brisbane/60 (BX-35) (egg): NIBSC\*
    - B/Texas/2/2013 Wt. (egg): NIID\*
    - B/Brisbane /46/2015 Wt. (egg): TGA\*
    - B/Brisbane/60 (BX-35) (cell): NIBSC\*
  
- **WHO Recommended Strain for 2017–18: Victoria lineage-B/Brisbane/60/2008-like viruses**
  - **Candidate Vaccine Viruses (egg derived):** B/Brisbane/33/2008 (Wt.); B/Brisbane/60/2008 (Wt., NYMC BX- 31, 31B, 31-CL, 33, 33B, 35) B/Bangladesh/5945/2009 (NYMC BX-37); B/Hong Kong/259/2010 (Wt., NYMC BX- 43, 43A, 43B); B/Nevada/3/2011 (Wt., NYMC BX-47); B/Texas/2/2013 (Wt., BX-53A, 53B, 53C); B/Brisbane/46/2015 (Wt.) & B/Florida/78/2015 (Wt.).
  - **Candidate Vaccine Viruses (cell culture derived):** B/Brisbane/63/2014 & B/Florida/33/2014
  - This strain was included as “B-Strain” for Trivalent and Quadrivalent Vaccine in 2016-17 season
  - Recommended for 2017 SH season

# Available Reagents for B-strain (Victoria lineage)

- **Reagents Available from CBER are being used for the current season**
  - **Reference Antigen For Egg Derived**
    - **B/Brisbane/60/2008: CBER Lot 77....is available**
    - *B/Brisbane/60/2008: NIBSC\* & TGA\**
    - *B/Brisbane/60 (BX-35): NIBSC\**
    - *B/Brisbane/46/2015: TGA\**
    - *B/Texas/2/2013: NIID\**
  - **For Cell Derived**
    - **B/Hong Kong/259/2010: CBER Lot B(v)-Ag-1604....is available**
    - **B/Brisbane/60: CBER**
    - *B/Brisbane/60/2008 (BX-35): NIBSC\**
- **CBER Antiserum**
  - B (v)-Ab-1602 (preparation of additional lots is planned)

***\*(CBER approval of these reagents: case by case basis)***



# Influenza B for Quadrivalent Formulations (2nd B-Strain)

- **Current Vaccine Strain (2016–17 Season): B/Yamagata/16/88-lineage-B/Phuket/3073/2013-like virus**
  - B/Phuket/3073/2013: Wt.
  - B/Utah/09/2014: Wt.
  - **Reagents made available: B/Phuket/3073/2013 Wt. (egg): CBER, NIBSC, TGA & NIID**
    - B/Brisbane/9/2014 (egg): NIBSC
    - B/Utah/09/2014 (cell): CBER & NIBSC
- **WHO Recommended Second B Strain for 2017-18: B/Yamagata/16/88-lineage - B/Phuket/3073/2013-like virus**
  - **Candidate Vaccine Viruses (egg derived):** B/Phuket/3073/2013 (Wt., BVR-1B); B/California/12/2015 (Wt., BX- 59A, 59B); B/Brisbane/9/2014 (Wt.); B/Utah/09/2014 (Wt.); B/Arizona/10/2015 (Wt.); B/Hong Kong/432/2013 (Wt.); B/Hong Kong/3417/2013 (Wt., BX-57)
  - **Candidate Vaccine Viruses (cell culture-derived):**B/Brisbane/9/2014
  - Recommended for 2017 SH season

# Available Reagents for 2<sup>nd</sup> B-strain (Yamagata lineage)

- **Reagents Available from CBER are being used for the current season**
  - **Reference Antigen For Egg Derived**
    - **Wt. B/Phuket (egg): CBER Lot 80...is available**
    - *Wt. B/Phuket (egg): NIBSC\*, TGA\* & NIID\**
    - *Wt. B/Brisbane/9/2014 NIBSC\**
  - **For Cell Derived**
    - **Wt. B/Utah/09/2014: CBER Lot B(y)-Ag-1501....is available**
    - *Wt. B/Utah/09/2014:NIBSC\**
- **CBER Antiserum**
  - B(y)-Ab-1605
  - B(y)-Ab-1606
  - B(y)-Ab-1610

*\*(CBER approval of these reagents: case by case basis)*



# SRID Reagents: General Comments...1

- Only CBER authorized reagents should be used to test potency of vaccines marketed in the US (consult with CBER)
- CBER collaborates with other ERLs in calibration of reagents and can authorize the use of those reagents
- When CBER authorizes the use of reagent from other ERLs, users have to obtain these reagents directly from the ERL
- CBER recommends the use of reference antigen and reference antiserum from same source to avoid discrepancies (consult with CBER)
- The antisera lots may need to be changed over time due to limited amount produced per lot
  - Recommendation: Keep small supply of a current lot for bridging new lots in future

## SRID Reagents: General Comments...2

- Use of same reagents is desirable for Monovalent, Trivalent/Quadrivalent formulations (and follow-up stability studies)
- If required, suitability of egg or cell based reagents for alternative production processes needs to be evaluated (manufacturers and CBER can work together)
- For any inquires regarding CBER Reference Standards and Reagents availability and shipping, contact CBER Standards at [CBERShippingrequests@fda.hhs.gov](mailto:CBERShippingrequests@fda.hhs.gov)



**Thank You**